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Docket No.: V9661.0074  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Hsiang-Fu Kung et al.

Confirmation No.: 2232

Application No.: 10/801,648

Group Art Unit: N/A

Filed: March 17, 2004

Examiner: Not Yet Assigned

For: A COMBINED ADENO-ASSOCIATED  
VIRUS AND ADENOVIRUS COCKTAIL  
GENE DELIVERY SYSTEM FOR HIGH  
EFFICIENCY GENE EXPRESSION  
WITHOUT ELICITING IMMUNE  
RESPONSE IN IMMUNO-COMPETENT  
SUBJECTS

**INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

**Timing of Filing of the Information Disclosure Statement:**

☒ This IDS is being filed before the First Office Action<sup>1</sup>.

<sup>1</sup> The IDS should, where possible, include a certification under 37 C.F.R. §1.97(e).

- ☐ This IDS is being filed after the issuance of the First Office Action but before the issuance of a Final Office Action<sup>2</sup>.
- ☐ This IDS is being filed after the issuance of a Final Office Action but before the payment of the Final Fee<sup>3</sup>.

**Certifications:**

If checked, the undersigned makes the following statement(s):

- ☐ Statement under 37 CFR § 1.97(e):

Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement; or

No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

- ☐ Statement Under 37 C.F.R. § 1.704(d):

Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application less than thirty days prior to the filing of this information disclosure statement.

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<sup>2</sup> The IDS *must* include *either* a certification under 37 C.F.R. §1.97(e) *or* the fee set forth in 37 C.F.R. §1.17(p).

**Fee Required by 37 C.F.R. § 1.97(c)(2) or 1.97(d)(2):**

☐ If checked, the fee of \$180.00 set forth in 37 C.F.R. §1.17(p) is attached.

**Copies of Information:**

In accordance with 37 C.F.R. §1.98(a), the following are enclosed:

☒ A legible copy<sup>4</sup> of each document (or relevant portion thereof) is cited in the attached PTO/SB/08.

☐ With respect to any information which is not in English, a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, is attached. This concise explanation is provided by way of:

☐ A translation of the relevant portions of the non-English language information<sup>5</sup>;

☐ A statement explaining the relevant portions of the non-English language information;

☐ A copy [and, where not in the English language, a translation] of at least the relevant portion(s)<sup>6</sup> of the communication from a foreign patent

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<sup>3</sup> The IDS *must* include *both* a certification under 37 C.F.R. §1.97(e) *and* the fee set forth in 37 C.F.R. §1.17(p).

<sup>4</sup> A legible copy of the document is not required if (1) the information was previously cited by, or submitted to, the Office and considered by the Office in a prior U.S. application to which this application claims priority, provided that the prior application is properly identified in this IDS, and (2) the IDS submitted in the earlier application complies with 37 C.F.R. § 1.98(a) – (c). This exception does not apply to information cited in an International Application.

<sup>5</sup> 37 C.F.R. §1.98(a)(3)(ii) *requires* that an English language translation be provided when a translation of the document, or portion thereof, “is within the possession, custody or control of, or is readily available to any individual designated in 37 C.F.R. § 1.56(c).”

office in a counterpart foreign application in which the information was cited; or

☐ This information is contained in the specification of the present application.

☐ In accordance with 37 C.F.R. 1.98(d), copies of the cited documents are not enclosed as they were provided in application Serial No. \_\_\_\_\_, filed \_\_\_\_\_, which the present application relies upon for an earlier effective filing date under 35 U.S.C. 120.

**Materiality:**

Whether or not the information and references disclosed in this Information Disclosure Statement is “material” pursuant to 37 CFR 1.56, this submission is not intended to constitute an admission that any patent, publication or other information referred to therein is “prior art” for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

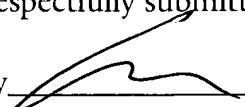
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<sup>6</sup> The relevant portion is that portion which indicates the degree of relevance found by the foreign patent office. This may be an explanation of which portion of the of the reference is particularly relevant, to which

In the event the actual fee is inadvertently not enclosed or if any additional fee during the prosecution of this application is not paid, the Patent Office is authorized to charge the underpayment to Deposit Account No. 50-2215.

Dated: January 31, 2005

Respectfully submitted,

By   
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PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>Substitute for form 1449A/B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/801,648-Conf. #2232	
			Filing Date	March 17, 2004	
			First Named Inventor	Hsiang-Fu Kung	
			Art Unit	N/A	
			Examiner Name	Not Yet Assigned	
Sheet	1	of	1	Attorney Docket Number	V9661.0074

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)					

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\*CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	XU, RA ET AL., 2001, "Perarol transduction of neuroendocrine cells and hepatocyte with an AAV insulin vector leading to Euglycemia in diabetic rats, Molecular Therapy, Vol. 3, No. 5, May 2001, Part 2 of 2	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.